Section H. Environmental Assessment

1. April 28, 1999

2. The Dow Chemical Company

3. 2030 Dow Center
Midland, Michigan 48674

4. Description of the proposed action

It is proposed that the Food and Drug Administration amend 21 CFR 177.1520 to include olefin basic polymers manufactured by the catalytic polymerization of ethylene and octene-1 having not less than 50 weight percent of polymer units derived from ethylene. These polymers have reduced stiffness, increased elasticity, and reduced softening and melting points compared to ethylene-octene copolymers with less than 20 weight percent octene. They are expected to be useful in a number of food packaging applications, either as a basic resin or as a minor component of the food contact surface, replacing a segment of the ethylene vinyl acetate copolymers, polyvinyl chloride, and ionomers of ethylene methacrylic acid copolymers. The food contact articles manufactured using these polymers will be properly used with all types of food at temperatures described by the conditions C through H of Table 2 of 21 CFR 176.170(c). The use of these new polymers will have the same impact on the environment as the existing products.

The copolymers that are the subject of this petition will be produced in manufacturing plants located in Texas Operations of The Dow Chemical Company in Freeport, Texas and in Louisiana Operations of The Dow Chemical Company in Plaquemine, Louisiana. Both of these sites are currently operated, integrated chemical manufacturing locations whose emissions to air and water from the site as a whole are regulated by permit and are in compliance with all applicable requirements. The area surrounding these manufacturing facilities is not expected to be adversely affected by the manufacture of any of the copolymers that are the subject of this petition.

Food packaging materials made from the polymers that are the subject of this petition will be manufactured by various producers of food packaging materials located across the country. The resulting films or other food contact articles will be used in patterns that correspond to the national population density and will be distributed across the country. Disposal is expected to occur nationwide with approximately 76% of the materials being mixed with household waste in landfills and 24% being incinerated.[1] The types of environments surrounding these disposal locations remain the same as for any other food-packaging material currently in use. There are no special considerations for the environment surrounding the disposal of these olefin copolymers when used as proposed. The manufacture, use and disposal of food packaging materials from these polymers is not expected to significantly change from, or increase the amount of, olefin and polyvinyl chloride materials currently in use for which the subject polymers are intended to compete and replace. Therefore, there is no significant impact on the surrounding environments as a result of the use of copolymers of ethylene and octene-1 having up to 50 % octene-1 to produce food packaging materials in place of those polymers currently used.

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[1] *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, May 1998.

5. Identification of chemical substances that are the subject of the proposed action.

The common name of the proposed food additive is copolymer of ethylene and octene-1. The polymers that are the subject of this petition have no less than 50 % by weight ethylene.

The Chemical Abstracts Services registry name, number and empirical formula are 1-Octene, polymer with ethene 26221-73-8 $(C_2H_4)_x(C_8H_{16})_y$.

The structural formula for representing ethylene-octene copolymers is

$$(\text{- CH2 - CH2-})_x\ (\text{- CH2- CH-})_y.$$
$$\qquad\qquad\qquad\qquad\qquad\qquad\qquad\qquad\quad |$$
$$\qquad\qquad\qquad\qquad\qquad\qquad\qquad\quad \text{CH2-CH2-CH2-CH2-CH2-CH3}$$

All possible combinations of ethylene and octene-1 monomers to produce the polymer above occur randomly.

Results of physical testing of two representative ethylene-octene-1 polymers are presented in the Table "Ethylene, 1-Octene Copolymer Property Data." Some of the differences in physical properties correspond to the high octene content of the copolymer such as polymer density, melting point, crystallization range and percent crystallinity. It is these properties which give the polymer processing and end-use advantages over the currently regulated products. On the other hand, the weight average and number average molecular weights, and the molecular weight distributions are similar to other *alpha*-olefin-based copolymers currently cleared for use in food contact applications under 21 CFR 177.1520.

Ethylene, 1-Octene Copolymer Property Data

Property	High Melt Index Product	High Octene Product
Melt Index, dg/min	49	1
Density, g/cc	0.884	0.856
Weight Percent Octene, FTIR	30.9	46.9
Weight Percent Octene, NMR	29.8	45.1
% Octene by IR, historical method	19.7	27.8
Weight Average Molecular Weight	40,600	140,000
Number Average Molecular Weight	21,100	66,000
Molecular Weight Distribution	1.9	2.1
DSC Melting Range, °C	-25 to 100	-25 to 65
Peak Melting Point, °C	81	39
DSC Crystallization Range, °C	-22 to 78	-38 to 35
Peak Crystallization Temperature, °C	64	20
Percent Crystallinity	16	7
Methyls/1000 C (ASTM D2238 B)	30.2	45.2
Vinyls/1000 C	0.03	0.03
Trans-vinylidenes/1000 C	0.2	0.2

6. Introduction of substances into the environment.

No extraordinary circumstances apply to the manufacture of the polymers that are the subject of this petition. Emission circumstances are adequately addressed by general or specific emission requirements promulgated by Federal, State or local environmental agencies. The proposed action does not threaten a violation of Federal, State or local environmental laws or requirements. Production associated with the proposed action does not adversely affect a species or critical habitat of a species determined to be endangered or threatened and entitled to special protection.

Little or no introduction into the environment of the copolymers subject to this action will result from their use because these copolymers are almost completely incorporated into food-packaging materials and essentially all of these copolymers are expected to remain with food packaging throughout use of the product.

Based on migration studies on the copolymers subject to this action, which were performed to demonstrate the safety of this additive, only very low levels of substances are expected to leach from these materials disposed in landfills. Therefore, the introduction of these substances into the environment will not threaten a violation of the Environmental Protection Agency's regulations in 40 CFR part 258 that pertain to landfills.

The copolymers subject to this action are composed of carbon, hydrogen and oxygen, elements commonly found in municipal solid waste.[2] The complete combustion of these copolymers will produce only carbon dioxide and water. Because these copolymers will be competing with and replacing very similar materials, adding them to waste that is combusted will not alter the emissions from municipal waste combustors. Therefore, we do not expect that the combustion of the additive will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i.e. 40 CFR part 60 or other relevant State and local laws.

7. Fate of emitted substances in the environment.

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of the subject copolymers, because, as discussed under Format Item 6, only small quantities, if any, of substances will be introduced into the environment as a result of use and /or disposal of these copolymers. Therefore, the use and disposal of these copolymers are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR parts 60 and 258.

8. Environmental effects of released substances.

No information need be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the subject copolymers, because, as discussed under Format Item 6, only small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of these copolymers. Therefore, the use and disposal of these copolymers are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR parts 60 and 258.

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[2] The levels of carbon, hydrogen and oxygen commonly found in municipal solid waste can be found in *Municipal Waste Combusors - Background Information for Proposed Guidelines for Existing Facilities*, EPA-450/3-89-27e, United States Environmental Protestion Agency, Office of Air Qualtiy Planning and Standards, Research Triangle Par, NC 27711; August 1989; Table 2.2-1.

9. Use of resources and energy.

It is proposed that the Food and Drug Administration amend 21 CFR 177.1520 to include olefin basic polymers manufactured by the catalytic polymerization of ethylene and octene-1 having not less than 50 weight percent of polymer units derived from ethylene. These polymers have reduced stiffness, increased elasticity, and reduced softening and melting points compared to ethylene-octene copolymers with less than 20 weight percent octene. They are expected to be useful in a number of food packaging applications, either as a basic resin or as a minor component of the food contact surface, replacing a segment of the ethylene vinyl acetate copolymers, polyvinyl chloride, and ionomers of ethylene methacrylic acid copolymers. The use of these new polymers will have the same impact on the environment as the existing products.

An estimate of the maximum yearly market volume of the copolymers that are the subject of this petition for the proposed food applications is provided in FAP 8B4601 Appendix 6.

The food-contact articles likely to be made from the subject copolymers are listed with the types and amount of food/container mass (where appropriate), and type of packaging currently used in these applications in the Table "Description of the food-contact articles and food applications affected by the proposed action." The highest volume use for ethylene/octene-1 copolymers regulated by any action on this petition will be in the replacement of films or components of films which currently use EVA and ethylene methacrylic acid copolymers (EMA). These films are used in wrapping dairy products, processed meats, dry food products, and snack foods.

Description of the food-contact articles and food applications affected by the proposed action.

Articles to be made with the subject co-polymers	**Types of food applications**	**Amount of food container will hold**	**Container mass**	**Type of packaging currently used for these applications (abbreviations are explained below)**
films	dairy products (e.g., cheese), processed meats, dry food (e.g., cereal, crackers), snack foods	not needed	not needed	PVC, EVA, EMA, olefin copolymers

closure liners or discs	Soda, water, beer, hotfill beverage, other food packaged under conditions of use C through H of Table 2 of 21 CFR 176.170 ©	not needed	not needed	PVC, EVA
Single service tubs and/or cups	Dairy products (e.g., yogurt)	8 ounces (avdp)	10 grams	LLDPE, HDPE cups, PP cups, HIPS
	margarine	8 ounces (avdp)	17 grams	HDPE tubs, cardboard containers

PVC = polyvinyl chloride
HIPS = High Impact Polystyrene
HDPE = high density polyethylene homopolymer,
LLDPE = linear low density polyethylene copolymers,
PP = polypropylene.
EVA = ethylene-vinyl acetate copolymers
EMA = ethylene-methacrylic acid ionomers

Dairy products are packaged in tubs or cups with lids that are currently made with LLDPE, HDPE, and PP. The ethylene/alpha olefin copolymers may be used as blends in small quantities with HDPE and PP to improve the low temperature performance, however, it would be prohibitively expensive with little or no benefit in performance to blend these copolymers with typical LLDPE.

The draft regulation proposed in this petition does not request a limit in the types of articles that could be prepared from ethylene/octene-1 copolymers. However, ethylene/octene-1 copolymers are not expected to be used in bottles or other rigid or semi-rigid containers. The stiffness and related performance criteria of resins for such articles limit the amount of octene-1 copolymer incorporated into the polyolefin to achieve sufficient properties for molded articles. The higher octene-1 containing copolymers may have utility in small quantities blended with HDPE and PP to modify the low temperature impact resistance of molded articles. However, the molded article would lose adequate structural stiffness with significant incorporation of higher octene-1 containing ethylene copolymers. The limited quantity of petitioned for polymers which could be blended with HDPE and PP and still retain stiffness properties for molded articles will not have an affect on the material which is currently recycled.

The improved properties (high impact strength, puncture resistance, clarity, and low heat seal initiation temperatures) which the higher octene copolymers provide are not of the type (i.e., barrier and stiffness) that will lead to replacement of dissimilar plastic materials such as PET. Therefore, there would be no changes in recycle pattern or behavior for any of the PET, HDPE, or polystyrene resins that are currently recycled.

The potential for FDA's action on this petition to impact solid waste management strategies can be assessed by comparing articles expected to be made with the subject copolymers to articles with which they will compete and that they will replace. The subject copolymers are expected to be used in making food-packaging films, gaskets for caps and closures, flexible food pouches, and molded containers. These new articles are expected to compete with other currently regulated food-packaging materials such as those shown in Section H. Table" Description of the food-contact articles and food applications affected by the proposed action." Articles made with the subject copolymers will be essentially the same in weight and volume as articles made with competing materials because the competing polymeric materials are very similar to the subject copolymers in composition. Thus, use of the subject copolymers will neither reduce nor increase the amount of packaging needed for the projected applications. The technical improvements associated with the subject copolymers are such that the articles made with these copolymers are likely to compete effectively with similar polymeric articles, but not with dissimilar food-packaging materials.

The articles made with the subject copolymers are very similar to the articles with which they will compete and, subsequently replace. There is little, if any, potential for FDA's action on this petition to have any impact on the solid waste management strategy of source reduction or on the resources involved with landfill volumes.

In addition, the agency's action is expected to have little, if any, impact on the solid waste management strategy of recycling, based on the following considerations. The bulk of food packaging material prepared from the petitioned for ethylene/octene-1 copolymers will be used in articles currently made from PVC, EVA, EMA and olefin copolymers. The plastic resin in articles made from the petitioned for polymers is not expected to be recycled. The rate of recycling of packaging made from LDPE, LLDPE and PP as presented in Table 7 of the current EPA waste report is negligible.[3] Also, the recycling of "other resins," which would include EVA to the extent that it is covered, is limited (30,000 tons of other materials recovered of the 3,130 thousand tons generated for a 0.96% generation recovered). There is currently negligible recycling of the articles the subject copolymers are expected to compete with and replace (containers of LDPE, LLDPE, PP or EVA, and food contact films[3]). Future recycling of food-contact films and containers to be used in the expected applications is not likely because of the difficulty of cleaning articles that have residual food adhering to the films and containers, and because these articles are currently made from a diversity of material types[4,5]. These

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[3] *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, May 1998

[4] *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, May 1998.

[5] J.S. Goff, "Plastic Film Recycling: A New Beginning," *Waste Age*, Vol. 26, No.2, February 1995, page 69.

circumstances make the recycling of articles listed in Section H. Table "Description of the food-contact articles affected by the proposed action." difficult to the point of not being feasible. Since articles made with the subject copolymers are expected to be very similar to the articles being replaced and there is essentially no recycling of these currently used articles, the expectation that articles made with the subject copolymers will also not be recycled is very unlikely to disrupt current recycling streams or to affect future recycling efforts.

Food packaging materials made from the polymers that are the subject of this petition are similar to already regulated materials that will be replaced. They will be manufactured by various producers of food packaging materials located across the country. The resulting films or other food contact articles will be used in patterns that correspond to the national population density and will be distributed across the country. Articles made with the subject copolymers will be essentially the same in weight and volume as articles made with competing materials because the competing polymeric materials are very similar to the subject copolymers in composition. The performance improvements associated with the subject copolymers (Section H. Table "Ethylene, 1-Octene Copolymer Property Data") are such that the articles made with these copolymers are likely to compete effectively with and replace similar polymeric articles, but not dissimilar food-packaging materials. Because of the manner in which these already regulated materials are handled, specifically, the lack of recycling of these materials, articles made form the subject copolymers will not have significantly different changes in the use and/or disposal patterns of food-packaging. Disposal is expected to occur nationwide and to be no different from the disposal of solid waste determined by the U.S. Environmental protection Agency (EPA)[6] (approximately 76% of the materials being mixed with household waste in landfills and 24% being incinerated). Since the ethylene/octene-1 copolymers proposed in this petition will replace part of the ethylene copolymers, PVC, EVA and EMA already regulated and in use, no increase in solid waste will occur as a result of amending the regulation to include these polymers.

Analysis of potential impact on energy that could result from FDA's action on this petition is not needed. The packaging materials currently used in the expected applications, identified in Section H. Table "Description of the food-contact articles affected by the proposed action" are very similar to the subject copolymers. Also, the recycling of food-packaging materials will not change as a result of FDA's approval of the subject copolymers because currently regulated materials are not now recycled nor are articles made with the subject copolymers expected to be recycled, as discussed above.

10. Mitigation measures.

There is no potential adverse environmental impact associated with the proposed action. The petitioned for polymers are intended to compete with already regulated and used, chemically similar copolymers. No new environmental impacts are expected.

11. Alternatives to the proposed action.

No potential adverse environmental impacts have been identified for the proposed action.

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[6] *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, May 1998

12. List of Preparers

Karen Glenn is a Technical Manager in The Environmental, Health and Safety Department of The Dow Chemical Company. She received a B.S. Education from Bowling Green State University of Ohio and an M.S. Chemistry from the University of Akron, Ohio. Ms. Glenn has been employed as a research chemist and R&D manager in various technical areas since 1980.

13. Certification:

The undersigned certifies that the information presented is true, accurate, and complete to the best of her knowledge.

(date) April 29, 1999

(signed) Karen Glenn

Karen Glenn
Technical Manager
Regulatory Management
The Dow Chemical Company